

DISTRICT OF NEVADA

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PHARMA TECH SOLUTIONS INC., et al.,

Plaintiffs,

V.

LIFESCAN INC., et al.,

Defendants.

Case 2:16-cv-00564-RFB-PAL

OPINION & ORDER

I. INTRODUCTION

Before the Court is Defendant's Motion for Summary Judgment (ECF No. 67). For the reasons discussed below, the Motion for Summary Judgment is granted.

II. BACKGROUND

This is a patent infringement case involving two competitors in the market for blood glucose monitoring. Plaintiff contends that Defendant infringed upon two of its patents for blood glucose monitoring test strips, U.S. Patent No. 6,153,069 (“the ‘069 Patent”) and U.S. Patent No. 6,413,411 (“the ‘411 Patent”).¹ Defendant LifeScan is a leader in the market for glucose monitoring systems. Defendants LifeScan, Inc. and LifeScan Scotland, Ltd. are subsidiaries of Johnson & Johnson. The allegedly infringing product is LifeScan’s OneTouch Ultra glucose

¹ The ‘411 Patent was a continuation of the ‘069 and for purposes of this case is essentially the same. Therefore, the Court will consider the infringement claims together.

1 monitoring system. Plaintiff Pharma Tech develops, markets and distributes affordable medical
2 diagnostic tools to home users. In and around 2011, Pharma Tech was part of a group that
3 developed a glucose test strip known as “GenStrip.” The GenStrip was cleared for sale in the
4 United States by the FDA on November 30, 2012. The GenStrip is compatible with Lifescan’s
5 One Touch Ultra line of meters and, at the time, was the only third-party strip cleared by the FDA
6 for use in Lifescan’s meters. Pharma Tech’s parent corporation bought the ‘069 and ‘411 patents
7 in 2015 for \$250,000.
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9 Plaintiff filed the complaint in this case on March 14, 2016 claiming both literal
10 infringement and infringement under the Doctrine of Equivalents (“DOE”). (ECF No. 1).
11 Defendant filed a Motion to Dismiss on June 21, 2016. (ECF No. 34). This Court held a hearing
12 on March 13, 2017 in which it: (i) allowed Pharma Tech to file an amended complaint; (ii) ordered
13 expedited discovery, limited to the issue of infringement for the claim elements at issue on the
14 motion to dismiss, and (iii) invited LifeScan to move for summary judgment after this limited
15 discovery was completed. (ECF No. 50). Plaintiff filed an Amended Complaint on April 3, 2017.
16 (ECF No. 49). The parties entered a stipulation to dismiss Plaintiff’s literal patent infringement
17 claims on May 10, 2017. (ECF No. 58). Defendant filed the instant Motion for Summary Judgment
18 on July 24, 2017. (ECF No. 67). Plaintiff responded on August 28, 2017. (ECF No. 69). Defendant
19 replied on September 18, 2017. (ECF No. 73).
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24 **III. THE PATENTS & THE ALLEGED INFRINGING PRODUCTS**

25 **A. The ‘069 AND ‘411 Patents**

26 Pharma Tech alleges infringement of its ‘069 and ‘411 patents. The ‘069 and ‘411 patents
27 have the same inventors. The ‘411 patent is a continuation of the ‘069 patent, and thus has the
28 same written description or “specification.”

1 The '069 and '411 patents describe a system for measuring blood glucose levels. The
2 system uses a sensor, which is inserted into a meter and whetted by a "sample fluid" (e.g. blood).
3 The meter then "imposes a known potential across the [sensor's] electrodes and measures the
4 resulting . . . current at specific time points." Current measurements are converted by a
5 microprocessor into equivalent glucose concentrations. According to Pharma Tech, the novel
6 feature of the '069 and '411 patents is a system for performing a safety check to detect errors in
7 blood glucose readings. The system covered by the '069 and '411 patents performs the safety
8 check by taking and comparing two different glucose concentration readings before reporting a
9 result to the user.
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11 The claims of the '069 and '411 patents refer to "Cottrell current readings." As described
12 in the patents, Cottrell current readings are readings of "electric current [that] decay [i.e., lessen]
13 with time in accordance with [a known equation]." To facilitate the claimed comparison in the
14 '069 and '411 patents, two Cottrell current readings are taken at different times, with the later
15 reading "occurring at a second predetermined time following the first predetermined time." The
16 Cottrell current readings are then "converted . . . to equivalent glucose . . . concentrations." Those
17 glucose concentrations are compared to see whether they are within a prescribed percentage of
18 each other. According to the patents, "[r]esults outside of the acceptable limits would indicate
19 some problem with the system."
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22 The initial patent application for the '069 patent overcame various rejections by the PTO.
23 After responding to the PTO's rejections and amending the claims, the applicant's accepted claims
24 of '069 and '411 patents all include limitations teaching a method for creating and comparing
25 separate measurements of "analyte concentration." For example, claim 1 of the '069 Patent
26 discloses:
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1 “[a] microprocessor means for *converting* the first Cottrell current reading
2 into a *first analyte concentration* measurement using a calibration slope
3 and an intercept specific for the first Cottrell current measurement, for
4 converting the at least one additional Cottrell current reading into an
5 *additional analyte concentration* using a calibration slope and an intercept
6 specific for the at least one additional Cottrell current measurement, and for
7 *comparing the first analyte concentration measurement with the at least*
8 *one additional concentration measurement* to confirm that they are within
9 a prescribed percentage of each other” ‘069, 13:48-59 (emphasis added).

10 Claim 4 teaches “A device for obtaining measurements of an *analyte* contained in a sample in
11 order to determine the *concentration of analyte* in the sample.” ‘069, 14:6-8 (emphasis added).

12 Claim 5 and Claim 6 assert “A system for obtaining measurements of *analytes* contained in a
13 sample in order to determine the *concentration of the analyte* in the sample.” ‘069, 14:52-54,
14 15:33-35 (emphasis added). The Court thus finds that all of the independent claims of the ‘069
15 patent (and the ‘411 patent) require or reference a device or system for measuring “analyte
16 concentration.”²

17 **B. LifeScan’s Allegedly Infringing System**

18 The LifeScan system does not compare “analyte concentration.” Rather, the LifeScan
19 system conducts its safety or quality check on the two samples by comparing “electric currents”
20 that are measured at two separate electrodes to determine if those electric current measurements
21 are within a specified range of each other. Only after determining by a particular algorithm that
22 the two current measurements are sufficiently close to each other does the LifeScan system then
23 combine the currents into a single glucose concentration measurement. The LifeScan system does
24 not compare separate concentration measurements. Rather it generates only one measurement
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28 ² The ‘411 similarly references systems for measuring analyte concentration. ‘411, 13:40-
50 (claim 1), 14:26-37 (claim 4), 15:5-19 (claim 7) and 16:17-29 (claim 8).

1 after conducting a validity check based upon the comparison of the two electric current
2 measurements.

3 4 5 **IV. LEGAL STANDARD**

6 Plaintiff brings its infringement claims under the “doctrine of equivalents.” Pozen, Inc. v.
7 Par Pharm., Inc., 696 F.3d 1151, 1167 (Fed. Cir. 2012). In order to establish infringement under
8 the “doctrine of equivalents” a patentee must “prove that the accused device contains an equivalent
9 for each limitation not literally satisfied.” Wi-Lan, Inc. v. Apple, Inc., 811 F.3d 455, 463 (Fed.
10 Cir. 2016).

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12 Defendant argues that Plaintiff’s infringement claims are barred by both amendment-based
13 and argument-based prosecution history estoppel. Under the doctrine of amendment-based
14 estoppel, an amendment during patent prosecution that narrows a claim for reasons of patentability
15 is “presumed to be a general disclaimer of the territory between the original claim and the amended
16 claim.” Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740 (2002). “[T]he
17 presumption [is] that the patentee has surrendered all territory between the original claim limitation
18 and the amended claim limitation.” Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344
19 F.3d 1359, 1365 (Fed. Cir. 2003) (en banc). There are three ways a patentee can rebut the Festo
20 presumption, once it has been established. The only one at issue here is the “tangential relation”
21 exception, which creates an exception where “the rationale underlying the amendment [bore] no
22 more than a tangential relation to the equivalent in question.” Id. The applicability of the
23 “tangential relation” exception is a question of law for the court to decide “on the basis of the
24 public record [from the prosecution history].” Biagro Western Sales, Inc. v. GrowMore, Inc., 423
25 F.3d 1296, 1306 (Fed. Cir. 2005). In considering this exception, the court “ask[s] ‘whether the
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1 reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged
2 equivalent.”” Integrated Tech. Corp. v. Rudolph Techs., Inc., 734 F.3d 1352, 1358 (Fed. Cir. 2013)
3 (quoting Festo, 344 F.3d at 1369). The inquiry ““focuses on the patentee’s objectively apparent
4 reason for the narrowing amendment,’ which ‘should be discernable from the prosecution history
5 record.”” Id. (quoting Festo, 344 F.3d at 1369). If a tangential rationale for the amendment “is not
6 objectively apparent from the prosecution history” then the patent owner has not met its burden on
7 the issue. Id.

9 Prosecution history estoppel can also occur where an applicant surrenders “claim scope
10 through argument to the patent examiner (‘argument-based estoppel’).” Voda v. Cordis Corp., 536
11 F.3d 1311, 1325 (Fed. Cir. 2008). “[A]n applicant can make a binding disavowal of claim scope
12 in the course of prosecuting the patent, through arguments made to distinguish prior art references.
13 Such argument-based disavowals will be found, however, only if they constitute clear and
14 unmistakable surrenders of subject matter.” Cordis Corp. v. Medtronic Ave, Inc., 511 F.3d 1157,
15 1177 (Fed. Cir. 2008). “[T]he relevant inquiry is whether a competitor would reasonably believe
16 that the applicant had surrendered the relevant subject matter.”” PODS, Inc. v. Porta Stor, Inc., 484
17 F.3d 1359, 1368 (Fed. Cir. 2007) (quoting Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570,
18 1583 (Fed. Cir. 1995)). The presumption of surrender “applies to all claims containing the [added]
19 [l]imitation, regardless of whether the claim was, or was not, amended during prosecution.” Felix
20 v. Am. Honda Motor Co., 562 F.3d 1167, 1182-83 (Fed. Cir. 2009) (internal citations and
21 quotations omitted). Therefore, if a subsequent patent is a continuation of a patent that surrendered
22 the scope of a claim, the claim scope is surrendered in the subsequent patent as well.

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1 **IV. ANALYSIS**

2 **A. Prosecution History of the ‘069 Patent³**

3 The application giving rise to the ‘069 Patent was filed on February 9, 1995. The original
4 language of Plaintiff’s disputed claim disclosed a means for “creating an electric circuit between
5 [a] first electrode and [a] second electrode through [a] sample,” “measuring Cottrell current
6 through said sample” and “visually displaying results of said measurement.” Plaintiff admits that
7 the claims attached to the original application were broad enough to essentially cover any test strip
8 with two electrodes. In an Office Action dated March 21, 1997, the examiner rejected the claims
9 with reference to prior art that also featured two working electrodes.
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12 On October 27, 1997, the applicant responded to the rejection with a Response to Office
13 Action. The applicant amended certain claims (4, 17, 66-69) and cancelled the rest. The applicant
14 made the following amendment to claim 4 (underlined text is new):

15 e) means for measuring a first Cottrell current reading through said sample at a first
16 predetermined time after said electrical potential is applied and for obtaining at least one
17 additional Cottrell current reading through said sample, said at least one additional Cottrell
18 current reading occurring at a second predetermined time following said first
19 predetermined time,
20 f) means for converting said first Cottrell current reading into a first analyte concentration
21 measurement, and for converting said at least one additional Cottrell current reading into
22 an additional analyte concentration measurement, and for linearly comparing said first
23 analyte concentration measurement to said additional analyte concentration
24 measurement...

25 This language was also rejected by the examiner and was further refined over a series of
26 amendments, but the language concerning “converting” at least two Cottrell current readings to
27 “analyte concentration” measurements and “comparing the first analyte concentration
28 measurement with the at least one additional concentration measurement” remained in the final
approved ‘069 Patent.

³ If Plaintiff surrendered the infringement claim in the prosecution of the ‘069 Patent, it surrendered the claim in the ‘411 Patent as well. *Felix*, 562 F.3d at 1182-83. For this reason, the Court only needs to look to the prosecution history of the ‘069 Patent in analyzing infringement.

1 In attempting to distinguish its claims from prior art, the applicant made the following
2 arguments concerning the comparison of *multiple analyte concentration readings* during the
3 course of patent prosecution:

- 4 • In supporting its October 27, 1997 amendment, the applicant argued, “Pollman likewise
5 does not suggest the present claimed means for ***comparing the concentration*** derived
6 from the first measurement and at least one additional ***concentration*** derived from an
7 additional measurement to verify the results.” ‘069 Prosecution History at
8 069PH_00000131-132. (emphasis added).
- 9 • In that same submission, the applicant distinguished Szuminsky ‘564 on the grounds that
10 the claimed invention “verif[ies] the result by ***comparing concentrations*** determined at
11 different times during the measurement.” ‘069 Prosecution History at 069PH_00000132.
12 (emphasis added).
- 13 • In the remarks section to the September 27, 1999 amendment, the applicant noted that the
14 Walling and Szuminsky patents “do not. . . disclose taking multiple ***analyte***
15 ***concentration measurements and comparing such...***” 069 Prosecution History at
16 069PH_00000199. (emphasis added).
- 17 • In support of its May 12, 2000 Amendment, the applicant distinguished the White patent
18 by arguing: “That operation in White (‘516) differs from the present invention in the
19 following respects. First, in the present invention the two different Cottrell current
20 readings are ***converted into first and second analyte concentration measurements***.
21 Further, in the present invention the ***first and second analyte concentration***
22 ***measurements based on the first and second current readings are compared to each***
23 ***other*** to confirm that they are within a prescribed percentage of each other...” ‘069
24 Prosecution History at 069PH_00000219-220. (emphasis added).
- 25 • In that same submission, the applicant argued that the Walling patent “does not . . .
26 compare the first and second analyte concentration measurements to each other, as in the
27 present invention.” ‘069 Prosecution History at 069PH_00000219-220.

1 Plaintiff points out that the applicant also distinguished its claims from the White patent by
2 arguing that “White discloses determining whether a Cottrell current reading is proper by a
3 complicated mathematical inverse ratio of the times square root. In contrast to the teachings in
4 White the present invention compares analyte concentration readings at different times.” ‘069
5 Prosecution History at 069PH_00000200. They argue that it was the linear comparison of the two
6 readings, as compared to White’s “complicated mathematical inverse ratio of the times square
7 root” that was the primary focus of their differentiation from White, rather than the conversion to
8 and comparison of analyte concentration measurements.

9 10 **B. Amendment-Based Estoppel**

11 Defendants argue that when the applicant to the ‘069 Patent amended its application to add
12 the language requiring the conversion from Cottrell current readings to analyte concentration
13 measurements and the comparison of those concentration measurements, they surrendered any
14 claims to infringement based on patents that do not compare analyte concentration measurements.
15 As their patent compares Cottrell current readings, rather than analyte concentration
16 measurements, they argue that Plaintiff surrendered the territory—where their invention exists—
17 between the original claim and the amended claim. Plaintiff argues that the comparison of analyte
18 concentration measurements was tangential to the real purpose of the amendment, which was to
19 require a linear comparison of multiple measurements, and therefore they did not surrender claims
20 to equivalents that do not include analyte concentration comparisons. This is a question for the
21 Court to decide based on the prosecution history record. Biagro, 423 F.3d at 1306. The Court finds
22 that Plaintiff has not overcome the Festo presumption and agrees with the Defendant that summary
23 judgment is appropriate.

24 When the ‘069 Patent applicant amended its claim from simply measuring Cottrell current
25 through two electrodes to requiring the conversion of Cottrell current readings to analyte
26 concentration measurements and comparing the measurements, they established a presumption
27 that they surrendered all territory between those two claims. Festo, 344 F.3d at 1365. As
28 Defendant’s patent compares two Cottrell currents, but does not convert those currents to analyte

1 concentration measurements before performing the comparison, there is a presumption that
2 Plaintiff surrendered its claim to the type of invention taught in Defendant's patent. That is
3 because the initial application for the '069 patent did not distinguish between measurements of
4 current versus measurements of analyte concentration. The primary independent (and dependent)
5 claims (Claims 1-17, 58-60 and 65-69) in the initial application were rejected as being obvious
6 and anticipated by prior art. The examiner's rejection on March 10, 1997 relied upon prior art
7 from U.S. Patent No. 5,385,846 to Kuhn ("Kuhn"), U.S. Patent No. 5,288,636 to Pollman
8 ("Pollman") and U.S. Patent No. 5,108,564 to Szuminsky ("Szuminsky"), which similarly taught
9 inventions involving two electrodes with sensors measuring electric currents across testing strips.

10 Plaintiff argues that the language regarding the conversion to analyte concentration
11 measurements was merely tangential to the overall purpose of the amendment. However, this
12 tangential rationale is not "objectively apparent from the prosecution history. " Integrated Tech.
13 Corp., 734 F.3d at 1358 (quoting Festo, 344 F.3d at 1369). Although Plaintiff points to arguments
14 made during prosecution that differentiated between the '069 Patent applicant's claims and prior
15 art – the White patent in particular – based on the linear comparison of two measurements, the
16 '069 Patent applicant also consistently relied on the comparison of two *analyte concentration*
17 *measurements* as a distinguishing feature of its claims.

18 Furthermore, as Plaintiff points out that White was not one of the prior art references relied
19 upon by the examiner in the original rejection that led to the analyte comparison amendment
20 Defendant focuses on. Instead, the examiner pointed to three existing patents, U.S. Patent No.
21 5,385,846 to Kuhn ("Kuhn"), U.S. Patent No. 5,288,636 to Pollman ("Pollman") and U.S. Patent
22 No. 5,108,564 to Szuminsky ("Szuminsky"), which already featured two working electrodes. As
23 discussed above, in supporting the October 27, 1997 amendment that is the focus of Defendant's
24 argument, the applicant differentiated Pollman because it "does not suggest the present claimed
25 means for comparing the concentration derived from the first measurement and at least one
26 additional concentration derived from an additional measurement to verify the results" and
27 Szuminsky on the grounds that the claimed invention "verif[ies] the result by comparing
28 concentrations determined at different times during the measurement." '069 Prosecution History

1 at 069PH_00000131-132. This explanation did not emphasize a “linear comparison” of
2 measurements or a unique mathematical formula or unique algorithm. Rather, based on Plaintiff’s
3 own analysis of the prosecution history, White’s “complicated mathematical inverse ratio of the
4 times square root” was not the focus of the amendment that originally added the conversion and
5 comparison of analyte concentration measurements. This is further evidence that the comparison
6 of *analyte concentration measurements* was, at a minimum, a significant aspect of the amendment,
7 rather than merely tangential to the linear comparison of multiple measurements. Based on this
8 record, Plaintiff has not overcome the presumption of surrender based on the narrowing
9 amendment and the Court finds that amendment-based estoppel is appropriate. As Plaintiff
10 surrendered this claim in the ‘069 Patent and the ‘411 Patent was a continuation of the ‘069 Patent,
11 Plaintiff has surrendered the claim in the ‘411 Patent as well. Felix, 562 F.3d at 1182-83.

12 13 **C. Argument-Based Estoppel**

14 The Court incorporates by reference its earlier analysis and findings from this Order regarding
15 amendment-based estoppel to the analysis here. The same excerpts from the record that support
16 the finding that the comparison of analyte concentration measurements was not merely tangential
17 to the ‘069 Patent applicant’s amendments also establish the applicability of argument-based
18 estoppel to the Plaintiff’s claims in this litigation. In prosecuting the patent, the ‘069 Patent
19 applicant consistently referenced the conversion to and comparison of analyte concentration
20 measurements. Based on these statements, it would have been reasonable for a competitor to
21 believe that the ‘069 Patent applicant had surrendered the territory in question. PODS, Inc. v. Porta
22 Stor, Inc., 484 F.3d at 1368. Therefore, the Court finds that argument-based estoppel is applicable
23 as well.

24 25 **V. CONCLUSION**

26 **IT IS THEREFORE ORDERED** that Defendant’s Motion for Summary Judgment (ECF
27 No. 67) is GRANTED.
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1 **IT IS FURTHER ORDERED** the Clerk of the Court shall enter judgment accordingly
2 and close this case.

3 **DATED:** October 23, 2018.

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RICHARD F. BOULWARE, II
UNITED STATES DISTRICT JUDGE